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021323 HM22/1023
TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON MA 02110

EXAMINER
HUNT, J

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/315,355

Applicant(s)
Keesee et al.

Examiner
Jennifer Hunt

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 30, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24, 25, 50-52, and 54-63 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 25, 50-52, and 54-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Response to Amendment

1. Acknowledgment is made of applicant's cancellation of claims 39-49 and 53, and addition of new claims 55-63. Claims 24-25, 50-52, and 54-63 are pending in the application and under consideration.

Claim Rejections Withdrawn

2. All previous grounds of rejection of claims 39-49 and 53 are withdrawn in light of the cancellation thereof.

3. The rejection of pending claims 24-25, 50-52 and 54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (written description rejection) is withdrawn in light of the amendments thereto.

4. The grounds of rejection of pending claims 24 and 54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (enablement rejection) is withdrawn in light of the amendments thereto, and applicant's arguments.

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Claim Rejections Maintained

5. The grounds of rejection of claims 25 and 50-52 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (enablement rejection) is maintained for reasons of record, and applied to newly added claims 55-63.

Claims 25, 50-52, and 55-63 are all now drawn to detecting cervical carcinoma by administering a binding moiety which binds to a target nucleic acid which is indicative of cervical cancer, where the binding moiety is capable of binding to SEQ ID NO:47. Thus the binding moiety broadly encompasses any sort of molecule, provided only that it binds to SEQ ID NO:47. Further, the nucleic acid which is bound by the binding moiety encompasses any nucleic acid molecule which the binding moiety binds to, and therefor includes a broad range of nucleic acids. Thus the claims as recited include sequences which possess only minimal homology or conformational similarity to SEQ ID NO:47. The breadth of the claims encompasses binding moieties which bind to any number of possible nucleic acid molecules other than SEQ ID NO:47, including variants due to degeneracy of the genetic code, and further including any nucleic acid of any length, providing that small fragments or structural attributes of SEQ ID NO:47 are included. Thus the claims encompass a large number of possible binding moieties, as well as a large number of possible nucleic acid molecules.

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The teachings of the specification are far more limiting: the specification teaches detecting cervical cancer by detecting the presence of a polypeptide or specific fragments thereof which correspond to SEQ ID NO:1-10. The specification fails to teach detection of cervical carcinoma by detecting the presence of even one specific nucleic acid molecule, and thus also fails to teach the broadly claimed detection methods which encompass any binding moiety which is capable of binding SEQ ID NO:47, and any nucleic acid molecule bound by the moiety.

The disclosure of one protein which is useful for diagnosing cervical cancer is insufficient support under the first paragraph of 35 U.S.C 112 for claims which encompass diagnosing cervical cancer by forming a complex between and nucleic acid and any binding moiety which binds to SEQ ID NO:47, thus encompassing any number of binding moieties and nucleic acids, including those yet undiscovered. The courts have held that:

“Inventor should be allowed to dominate future patentable inventions of others where those inventions were based In some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not In compliance with the first paragraph of U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill In the art; In cases involving predictable factors, such as

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mechanical or electrical elements, a single embodiment provides broad enablement In the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; In cases involving unpredictable factors, such as chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.”In re Fisher 427 F.2d 833, 166 USPQ 18 (CCPA 1970)

The specification provides no guidance or objective evidence to support the broadly claimed genus of molecules as useful in cervical cancer diagnostics. Thus the claims include variants and full length molecules which would fail to predictably correlate to cervical cancer, or to the polypeptide which they are supposed to encode.

Applicant argues that the claims as amended do not encompass a broad scope of nucleic acids which might not be diagnostic of cervical cancer; that the instant claims are limited to SEQ ID NO:47. Applicant's arguments filed 7/30/2001 have been fully considered but they are not persuasive.

As set forth above, the claims encompass detection of cervical cancer using any number of possible binding moieties, or nucleic acid molecules, and encompass numerous species, including non-diagnostic species, and species yet undiscovered.

Thus as set forth above, one of skill in the art would not be enabled to practice the invention as claimed. The claims are drawn to detecting any of a large number of possible

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nucleic acid molecules to detect cervical cancer. The nucleic acid molecule can be of any length, and contain numerous substitutions (based on the degeneracy of the genetic code). The teachings of the specification relied upon for enablement are insufficient because they merely correlate detection of a single polypeptide to cervical cancer. There is no guidance or objective evidence that the broadly recited binding moieties and nucleic acid molecules would function as instantly claimed. Thus one of skill in the art would not be enabled to practice the invention as claimed.

New Grounds of Rejection

Specification

6. The amendment filed 7/30/2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The nucleic acid sequence of SEQ ID NO:47 and 48 is not supported by the disclosure as originally filed. Applicant cites for support, page 7, lines 11-15 of the instant specification, which applicant argues incorporates Honore et al. (1994) Gene 151:291-296 by reference. This citation fails to provide support for the nucleic acid sequences because the portion of the specification that incorporates Honore et al. is drawn specifically to a protein sequence, IEF SSP 9502, and thus fails to provide support for a nucleic acid sequence.

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It is further noted that the attempt to incorporate subject matter into this application by reference to Honore et al. (1994) Gene, 151:291-296 is improper because there is no accompanying affidavit stating that the amendatory material consists of the same material incorporated by reference.

See MPEP 608.01(p):

The filing date of any application wherein essential material is improperly incorporated by reference to a foreign application or patent or to a publication will not be affected because of the reference. In such a case, the applicant will be required to amend the specification to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Applicant is required to cancel the new matter in the reply to this Office action.

7. Claims 24-25, 50-52, and 54-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims recite SEQ ID NO:47, which is not supported by the disclosure as filed. As set forth above, applicant cites for support, page 7, lines 11-15 of the instant specification, which applicant argues incorporates Honore et al. (1994) Gene 151:291-296 by reference. This citation fails to provide support for the nucleic acid sequences because the portion of the specification

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that incorporates Honore et al. is drawn specifically to a protein sequence, IEF SSP 9502, and thus fails to provide support for a nucleic acid sequence.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.


Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

October 16, 2001


ANTHONY G. CAPUTA
SUPERVISOR/ PATENT EXAMINER
TECHNOLOGY CENTER 1000